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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,749	05/10/2005	Lawrence Allan Lynn		7983

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EXAMINER	
MEHTA, BHISMA	
ART UNIT	PAPER NUMBER
3767	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

ED

Office Action Summary	Application No.	Applicant(s)	
	10/533,749	LYNN, LAWRENCE ALLAN	
	Examiner	Art Unit	
	Bhisma Mehta	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 May 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the tube defining at least one internal diameter where the diameter is variable must be shown or the feature(s) canceled from the claim(s). Also, the tube defining at least one internal diameter and including an enlarged portion having an increased internal diameter adjacent at least one element must be shown or the feature(s) canceled from the claim(s). Also, the reservoir fluid-locked with a catheter must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet"

pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: 220, 204, 206, and 208. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: 235 and 270. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended.

Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Priority

4. It is noted that this application appears to claim subject matter disclosed in prior Application No. PCT/US02/35163, filed November 4 2002. A reference to the prior application must be inserted as the first sentence(s) of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e), 120, 121, or 365(c). See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, 121, or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of

four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the

petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

Specification

5. The abstract of the disclosure is objected to because it contains legal phraseology. Correction is required. See MPEP § 608.01(b).

6. The disclosure is objected to because of the following informalities:

a. There are numerous grammatical and punctuation errors throughout the specification. For example, see lines 10-13 of page 12 and lines 21-24 of page 15.

b. The use of "100s" in line 12 of page 15 appears to be an error.

c. In lines 18 and 23 of page 16, "404" should be "403".

d. In line 10 of page 17, it appears that 'catheter 410" should be "catheter hub 410".

Appropriate correction is required.

7. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The specification fails to disclose the volume reducer configured to reduce the volume within the tube by a plurality of discrete volumes and the mixture defining a predetermined concentration of at least one antimicrobial and anticoagulant.

Claim Objections

8. Claims 1-30 are objected to because of the following informalities:

There are numerous grammatical and punctuation errors throughout claims 1-30. For example, the "a indwelling portion" in line 2 of claim 1 should be "an indwelling portion". In line 3 of claim 7, there appears to be a word missing in "by a plurality discrete volumes". In lines 2 and 6 of claim 27, a punctuation mark is missing after "catheter" and "antimicrobial", respectively. Also, see line 1 of claim 11 ("wherein ___ volume reducer" and see line 2 of claim 15 ("surfaces" should be "surface").

Claim 1 recites the limitations "said indwelling portion" in lines 4-5 and 14-15, "said source" in lines 7-10, "said flush solution" in line 8, and "said catheter" in lines 14-15. There is insufficient antecedent basis for these limitations in the claim. Similar instances of insufficient antecedent basis are found throughout the claims. The catheter having an indwelling portion, the external fluid source, and the flush solution have not been positively recited, and, therefore, the use of "the" instead of "said" is suggested. Similarly, there is no antecedent basis for "said catheter portion" in line 4 of claim 7. Claims 8, 19, 20, 27, 29, and 30 have instances of insufficient antecedent basis similar to those noted in claim 1. There is no antecedent basis for "said tube" in line 2 of claims 25 and 26. In claims 19, 27, and 29, 'said blood vessel" should be replaced with "the blood vessel".

It should be noted that the specific examples given above are just some of the numerous grammatical and punctuation errors and instances of insufficient antecedent basis found in the claims. Appropriate correction is required.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

10. Claims 1-30 are rejected under 35 U.S.C. 102(e) as being anticipated by Ash (U.S. Patent No. 6,958,049). Ash discloses a catheter-flushing system having a tubing system (14, 16) and volume reducers (20, 22). The tubing system (14, 16) is in fluid connection with an indwelling portion of a catheter (10). The tubing system defines an internal volume and at least one proximal terminal including a seal (28, 30). The proximal terminal has intermittent connection with an external fluid source or a flush solution such as saline (lines 14-16 of column 5) or a mixture of a diluent and at least one of an anticoagulant and an antimicrobial agent (lines 25-36 of column 7). The volume reducer is considered

to be a plurality of clamps (20, 22). Activation of the volume reducers reduces the volume within the tubing system by a plurality of discrete volumes. As to claim 8, the system includes a tube (14, 16) having a distal end connectable to a catheter (10), an internal open space defining a variable internal volume, and a lumen extending through the tube. The volume reducer comprises at least one volume reducing element (20,22) mounted within the system where the elements comprise clamps. The volume reducer can be considered to be a pinch clamp and also defines opposing elongated opposing surfaces. The tube (14, 16) has a variable internal diameter (see lines 16-18 of column 6) and includes an enlarged portion as seen in Figure 1. As to claim 19, the fluid-lock system (10, 14, 16) has a distal portion which defines an indwelling portion and an internal space defining an internal volume. As to claims 27 and 29, the system includes a reservoir (14, 16) and a volume reducer (20, 22) configured for engaging the reservoir. As to claim 30, Ash discloses disposing the tubing system (14, 16) in fluid connection with an indwelling portion of a catheter (10), flowing flush solution from an external fluid source, sealing the proximal terminal of the tubing system, and reducing the internal volume of the tubing system though the use of a volume reducer.

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where

the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 1, 5-26, 29, and 30 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 5-9, 11-30, 32, 33, and 35 of U.S. Patent No. 6,689,109. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are all drawn to a system or method for maintaining the patency of a lumen of a catheter or for flushing a lumen of a catheter.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

Rantanen-Lee (U.S. Patent No. 5,035,399), Bierman (U.S. Patent No. 5,318,546), and Quah (U.S. Patent No. 6,592,558) teach tubing systems with volume reducers.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bhisma Mehta whose telephone number is 571-272-3383. The examiner can normally be reached on Monday through Friday, 7:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BM

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER